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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/226,597	01/07/99	PIMENTEL	J 585-017-84

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EXAMINER	
GABEL, G	
ART UNIT	**PAPER NUMBER**
1641	7

DATE MAILED: 07/05/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/226,597	Pimentel
Examiner	**Group Art Unit**
Gallene R. Gabel	1641

☒ Responsive to communication(s) filed on *Apr 18, 2000*

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-9* is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-9* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

DETAILED ACTION

Amendment Entry

1. Applicant's amendment and response filed 4/18/00 is acknowledged and has been entered. Claims 1, 7, and 8 have been amended. Claims 1-9 are pending and under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. In light of Applicant's amendment and response, the rejection to claims 1-5 and 9 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is, hereby, withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. In light of Applicant's amendment and response, the rejection to claims 1-9 under 35 U.S.C. 103(a) as being unpatentable over Cook et al. (US 5,919,451) in view of Laurent et al.

(EP 0310931) and Leclercq et al. (Reproduction, Nutrition, and Development, 1990, Abstract only) is hereby, withdrawn.

New Grounds of Rejection

4. Claims 1-9 under 35 U.S.C. 103(a) as being unpatentable over Cook et al. (US 5,919,451) in view of Leclercq et al. (Reproduction, Nutrition, and Development, 1990).

Cook et al. has been discussed in a previous Office Action in Paper No. 3.

Specifically, Cook et al. disclose a method for regulating growth of an animal or improving efficiency of the animal to convert its feed into desirable body tissue, i.e. lean. Cook et al. specifically disclose feeding an animal a food composition comprising an optionally liposome-encapsulated immunoglobulin or antibody that help protect the animal from disease or other antigens that can affect the animal's growth or efficiency. The animal is then passively immunized through oral administration of effective amounts of egg-derived materials containing avian antibodies which are obtained by immunizing egg-laying hens with specific antigens. Such antibodies can alter physiological processes that adversely affect growth and feed efficiency or they can be antibodies that are against diseases or against specific endogenous regulators of food intake or gastrointestinal mobility.

Cook et al. fail to disclose encapsulating antilipase antibodies into liposomes for incorporation into feed and further fail to teach a specific amount of antibody contained into the food composition of claim 6, specifically 25-1000mg/kg.

However, it has been maintained that the amount of antibody contained in a food composition should be a safe and effective quantity and such range in value therefore renders an amount that is representative of a result effective variable which the prior art reference has shown may be altered in order to achieve optimum results. It has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value of a result effective variable. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation." See pages 5 and 6 of the last Office Action in Paper No. 3.

Further, Leclerq et al. has been discussed in Paper No. 3.

One of ordinary skill in the art at the time of the invention would have reasonable expectation of success in encapsulating antilipase antibodies such as taught by Leclercq, into the liposome mixture of Cook for incorporation into food composition to regulate body weight of animals because Leclercq specifically taught that antilipase antibodies that are parenterally introduced to poultry lowers their lipid levels and Cook especially taught that by encapsulation into liposomes in feeds for oral administration, antibodies absorbed prandially are protected from gastric acids so that their efficacy and functionality in regulating metabolism are maintained. Further, oral administration of biochemical modulating compounds is a known, conventional, alternate and efficacious delivery system where large populations of animals are involved. Therefore, one of ordinary skill in the art would have been motivated to incorporate the teachings of Leclercq into the method and food composition of Cook because Cook taught that his method

provides advantage in large scale applications and wide variety of purposes for providing an easy and convenient mode of delivering antibodies that alter physiological processes and affect growth, health, weight, and feed efficiency of large population of animals such as those produced and raised for consumption.

Response to Arguments

5. Applicant's arguments with respect to claims 1-9 based on the combination of Cook, Leclerq, and Laurent have been considered but are moot in view of the new ground of rejection. Specifically, Examiner confers with applicant's contention that the Laurent reference is not relevant to what is claimed in the instant invention.

6. On the other hand, Applicant argues that the teachings of Cook and Leclerq are also not relevant to, and therefore teach away from, what is taught in the claimed invention.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Further, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208

USPQ 871 (CCPA 1981). Note that the new ground of rejection is based on the obvious combination of Cook et al. in view of Leclerq et al. See paragraph No. 4 and discussion thereafter.

7. Applicant's arguments filed 4/18/00 have been fully considered but they are not persuasive.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gail Gabel whose telephone number is (703) 305-0807. The examiner can normally be reached on Monday to Thursday from 7:00 AM to 4:30 PM. The examiner can also be reached on alternate Fridays from 7:00 AM to 3:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) ~~308-4027.~~ 305-3399 The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

6/28/00

Gail Gabel
Patent Examiner
Group 1641

LONG V. LE
PRIMARY EXAMINER
A.U. 1641